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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/272,809	03/19/1999	JOHN CLARK LAGARIAS	23070-943	6118

7590 06/29/2004

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EXAMINER
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HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/272,809

**Applicant(s)**

LAGARIAS, JOHN CLARK

**Examiner**

Ja-Na Hines

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-19 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-19 and 21-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

  
LYNETTE R. F. SMITH

SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1645

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 12, 2004 has been entered.

### ***Amendment Entry***

2. The amendment filed May 12, 2004 has been entered. The examiner acknowledges the amendment to the specification. Claims 2 and 20 have been amended. Claims 1 and 17 have been amended. Claims 1, 3-19 and 21-32 are under consideration in this office action.

### ***Response to Arguments***

3. Applicant's arguments filed May 12, 2004 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. The written description rejection of claims 1, 3-19 and 21-32 under 35

U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is still maintained in view of the lack of written description of the claims for failing to recite the precise definition of the polypeptides, the full breadth of the claims fail to meet the written description provision of 35 USC 112, first paragraph.

Applicants assert that the written description requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular known structure, thus the written description in this case should be withdrawn. However applicants' instant arguments fail to meet the standard referred to. Applicant has failed to prove that knowledge of the art of the disclosed function is sufficiently correlated to a particular known structure, i.e., the lyase domain. Applicant~~s~~ has failed to provide knowledge in the art of sufficient correlation, it is noted that applicants' instant specification does not show knowledge in the art of sufficient correlation, rather it shows applicants' assertion. Moreover, applicants failed to show a correlation between a function and the structure. It is well known in the art that sequence similarity does not necessarily correspond to a particular function. The claims encompass many possible variations and derivatives, including substitutions, insertions or deletions of any amino acids~~s~~ without any limitation. There must be some nexus between the structure of the protein encoded and that function of that protein. However, function cannot be predicted from the modification of the structure of the polypeptide. Without any

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limitation on the sequence identity besides the number of amino acids, the polypeptide comprising 190 to 400 amino acids fails to have an adequate written description. The specification fails to teach variants yet broadly claims such. The claims encompass sequences with amino acid additions or deletions yet fail to describe such polypeptides. Applicants have failed to describe the claimed polypeptides that exist independent of that function, i.e., lyase activity. The specification fails to teach the structure or relevant identifying characteristics of such polypeptides.

It is known in the art that even a single amino acid change can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the recitation of similar sequence identity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecules and the indicated similar biomolecule of known function and therefore lacks support.

Several publications document the unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Russell [J. Mol. Bio.244:332-350]; Skolnick et al., [Trends in Biotech, 18(1):34-39]; and Attwood, [Science, 290:471-473, (29 October 2000)].

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Applicants assert that the written description requirement is met because one skilled in the art would discern possession of the invention at the time of filing. However, the standard is that every patent must contain a written description of the invention sufficient to enable a person skilled in the art to which the invention pertains to make and use the invention. Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same. Here, the instant specification fails to meet that requirement and thereby fails to meet the written description requirement. One skilled in the art at the time of filing could not be deemed to know exactly what amino acids are comprised in a polypeptide comprising about 190 to 400 amino acids when applicants have failed to identify what amino acids. At best applicants said the polypeptide must comprise a lyase domain, however comprising a lyase domain does not tell one skilled in the art what amino acids are comprised in this polypeptide. Moreover, it enables the polypeptide to claim naturally occurring polypeptides and polypeptide not taught or disclosed in the instant specification. The fact that applicant has failed to disclose a polypeptide comprising an apoprotein polypeptide between about 190 amino acids to

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about 400 amino acids that comprises a lyase domain is further evidence that applicant lacked possession. Therefore, applicant has failed to prove that they were in possession of the invention at the time of filing.

Applicants assert that sequences referred to in Figure 2 show alignment of the chromophore (lyase) domains. Applicant specifically points to Cph1, Cph2, Cph3, Cph4, Cph5, Cph6, Cph7, and Cph8 which corresponds SEQ ID NO: 1-8. All of these sequences are greater than 400 amino acids long (748, 1276, 481, 1371, 891, 844, 950 and 750 amino acids in length). Clearly, these examples are not representative examples of apoproteins that are of about 190 to 400 amino acids that comprise lyase activity because they are not described as being about 190 to 400 amino acids. Moreover, these sequences refer to sequences from as applicants stated in the sequence listing as organism unknown, thus neither do these examples come from polypeptides selected from the group consisting of plant apoprotein, algal apoprotein and cyanobacterial apoprotein. AtphyA, AtphyB, AtphyC, AtphyD, AtphyE and Mcphy1b are all identified as SEQ ID NO:9. Nowhere in applicants' specification has applicant disclosed or identified that SEQ ID NO:9 has a lyase domain. Therefore, applicants other examples fail to adequately provide support in the written description. Although an actual reduction to practice, assuming one exists here, may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. In the context of this case, the disclosure of the way the invention was reduced to practice does not satisfy the more fundamental written description requirement set forth in the statute, i.e., that the specification shall contain a written

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description however, here applicant has merely disclosed that it obtained the sequences, but they have not identified them.

In absence of further guidance from Applicants, the skilled artisan would have to de novo discover what the appropriate amino acid are and what critical regions can and cannot tolerate such substitutions. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. The need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use for of the polypeptides. Therefore, a skilled artisan would be forced into undue experimentation to practice (i.e., make and use) the invention as is broadly claimed. Furthermore, one of skill in the art would not predict such a product would be structurally or functionally related to the instantly claimed polypeptide. Thus one of ordinary skill in the art could not make and/or use the invention as is broadly claimed. Such need for non-routine experimentation demonstrates that the specification is not enabled for to make and/or use the broadly claimed polypeptides. Accordingly, a skilled artisan would be forced into undue experimentation in order to make and/or use the invention as is broadly claimed. The instant specification fails to describe the claimed invention sufficient to show that the applicant was in possession of the claimed invention. Applicants' arguments are not persuasive. Therefore, the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines   
June 18, 2004